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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,858	03/02/2005	Hiroyoshi Hidaka	8279.829USWO	5428
23552	7590	10/31/2005	EXAMINER	
MERCHANT & GOULD PC			GEMBEH, SHIRLEY V	
P.O. BOX 2903			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55402-0903			1614	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/526,858	Applicant(s) HIDAKA ET AL.	
	Examiner Shirley V. Gembeh	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/9/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1614

DETAILED ACTION

Receipt is acknowledged of amendment filed 03/02/2005. Claims 5-10, 13, 15-17 are amended, claims 20-23 are cancelled; therefore claims 1-19 are pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 09, 2005, has been considered.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim lacks clarity. Does the composition comprise a compound of formula I and an antitumor agent, intended use confer no patentable weight to composition claims. Applicant is asked to clarify.

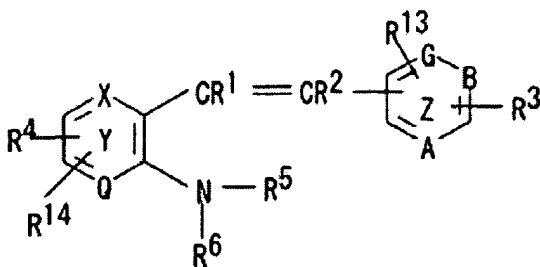
Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 (in part), 2-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hidaka et al., US 5,972,976.

Art Unit: 1614

Hidaka et al teach current claim 1, in part, a compound of formula I



(I)

at col. 2 lines 15+, wherein the

substituents of Rs' are the same as claimed by applicant at col. 2 lines 25-60, wherein R¹ and R² each represent hydrogen col. 2 lines 26-27, R³, R⁴, R¹³ and R¹⁴ at col. 2 lines 30, R⁵ is hydrogen at col. 2 line 39, R⁶ is phenylsulfonyl at col. 2 lines 46+, Ring Y is phenyl and Ring Z is 4-pyridyl at col. 2 lines 38+ as in current claim 2, wherein R¹ and R² each represents hydrogen col. 2 line 26-27, R³, R⁴, R¹³ and R¹⁴ represents hydrogen at col. 3 line 47, R⁵ is hydrogen at col. 2 line 39, R⁶ is phenylsulfonyl at col. 2 lines 46+, Ring Y is phenyl and Ring Z is 4-pyridyl at col. 2 lines 38+ as in current claim 3, wherein the pharmaceutical composition of formula 1 is

(E)-4-[2-[2-[N-[(p-methoxyphenyl)sulfonyl]amino]phenyl]ethenyl]pyridine,

at col. 4 line 53

as in current claim 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hidaka et al., US 5,972,976, in view of Goodman and Gilman, The Pharmacological Basis of therapeutics, and Ragaz et al., The New England J. of Med.

The chemical structure shows a fused ring system. The left ring is a six-membered ring with atoms X, Y, and Q. It has substituents R⁴, R¹⁴, and CR¹. The right ring is a five-membered ring with atoms G, Z, and A. It has substituents R¹³, B, and R³. The two rings are connected by a double bond between CR¹ and CR². The CR¹ group is also bonded to an N-R⁵ group, which is further bonded to an R⁶ group.

at col. 2 lines 15+, wherein the of Rs'

are the same as claimed by applicant at col. 2 lines 25-60, wherein R¹ and R² each represent hydrogen col. 2 lines 26-27, R³, R⁴, R¹³ and R¹⁴ at col. 2 lines 30, R⁵ is hydrogen at col. 2 line 39, R⁶ is phenylsulfonyl at col. 2 lines 46+, Ring Y is phenyl and

Art Unit: 1614

Ring Z is 4-pyridyl at col. 2 lines 38+ as in current claim 2, wherein R¹ and R² each represents hydrogen col. 2 line 26-27, R³, R⁴, R¹³ and R¹⁴ represents hydrogen at col. 3 line 47, R⁵ is hydrogen at col. 2 line 39, R⁶ is phenylsulfonyl at col. 2 lines 46+, Ring Y is phenyl and Ring Z is 4-pyridyl at col. 2 lines 38+ as in current claim 3, wherein the pharmaceutical composition of formula 1 is

(E)-4-[2-[2-[N-[(p-methoxyphenyl)sulfonyl]amino]phenyl]ethenyl]pyridine, at col. 4 line 53

as in current claim 4.

Goodman and Gilman teach instant claims 5, 14, wherein the antitumor agent is cisplatin a platinum compound at page 1269, wherein the composition contains another antitumor compound, as in instant claim 7, 9, 13, 15, 16, at page 1270.

Although the above cited references, did not teach mode of administration, it would have been obvious to one of ordinary skill to administer combinatory drugs either simultaneously, as in current claim 6, sequentially as in current claim 8 as this mode of administration is well known in the art of medicine and has been in practice, therefore, one of ordinary skill in the art would have combined the above cited references and be successful in administering the drug either simultaneously or sequentially as determined by the physician in charge.

Radiotherapy in medicine is a common practice, especially in cases of tumor, where surgical removal may be fatal. In some other instances, radiation is applied, before and after (see ref. Ragaz et al).

Art Unit: 1614

Therefore one of ordinary skill in the art would have been motivated to administer radiotherapy either simultaneously or before or after chemotherapy as positive results have been shown, where the size of the tumor is reduced.

Although the references, Hidaka in view of Goodman et al., did not teach using the specific compound with radiotherapy, the idea of combination therapy to treat tumors has been in effect a long time.

One of ordinary skill in the art would have known to combine the teachings of Hidaka in view of Goodman treat tumors using adjuvant radiotherapy and chemotherapy wherein the drugs of Hidaka with that of Goodman are used, and expect a successful result. The drug of Hidaka is a well known anti cancer drug and when combined with other drugs of anticancer effect a synergistic effect is seen (see page 1230 of Goodman), the same effect is seen with radiotherapy.

Thus, the claimed invention was prima facie obvious to make and use at the time it was made.

No claim is allowed.

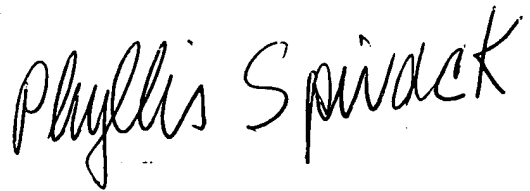
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembel whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVS
SVG
10/26/05

A handwritten signature in black ink that reads "Phyllis Spivack". The signature is written in a cursive, flowing style.

**PHYLLIS SPIVACK
PRIMARY EXAMINER**